24 February 2022
EMA/CHMP/83287/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Amversio

betaine anhydrous

On 24 February 2022, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Amversio, intended for the treatment of homocystinuria.

The applicant for this medicinal product is SERB S.A.

Amversio will be available as a 1 g oral powder. The active substance of Amversio is betaine, a natural substance acting as a methyl group donor (ATC code: A16AA06). Betaine reduces homocysteine levels in the blood by transforming homocysteine into the amino acid methionine through remethylation.

Amversio is a generic of Cystadane, which has been authorised in the EU since 15 February 2007. Studies have demonstrated the satisfactory quality of Amversio. Since Amversio is administered orally and contains betaine (without excipients) in the same concentration as Cystadane oral solution, a bioequivalence study versus the reference product Cystadane was not required. A question and answer document on generic medicines can be found here.

The full indication is:

Amversio is indicated as adjunctive treatment of homocystinuria, involving deficiencies or defects in:

- cystathionine beta-synthase (CBS),
- 5,10-methylene-tetrahydrofolate reductase (MTHFR),
- cobalamin cofactor metabolism (cbl).

Amversio should be used as supplement to other therapies such as vitamin B6 (pyridoxine), vitamin B12 (cobalamin), folate and a specific diet.

Amversio should be prescribed by physicians experienced in the treatment of homocystinuria.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.